REMARKS

Status of the Claims

The listing of claims above replaces all prior versions, and listings, of claims in the Application. The Applicants note that the Amendment and Response to the Office Action filed on October 29, 2007 was entered on December 10, 2007. Therefore, the insertions and deletions shown below are relative to the claims as amended by the Amendment and Response to the Office Action filed on October 29, 2007.

The Office Action indicates that the pending claims, claims 1-52, were rejected. By way of this Amendment and Response to the Office Action, claims 12, 18, 19, 38, and 49 are amended and claims 1-52 remain pending in the Application. The independent claims include claims 1, 18-20, 31 and 42. As further discussed below, the claim amendments and claim additions add no new matter to the Application.

Claim Objections and Rejection under 35 U.S.C. § 112, ¶ 2

Claim 12 was objected to because of an informality. Claim 12 has been amended to correct the error.

Claims 38 and 49 were rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been amended to correct the error.

Rejection under 35 U.S.C. § 103

Claims 1-7, 12-23, 25-27, 31-34, 37-38, 41-45, 48-49, and 52 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,868,763 issued to Spence et al. (hereinafter "Spence") in view of U.S. Patent No. 5,697,943 (hereinafter Sauer).

Claim 7 recites:

> "wherein each ring is configured to expand and contract to enable each respective vessel opening to change in diameter, and
>
> wherein the rings are configured to be structurally linked in a manner such that the first and second rings expand and contract in unison and such that the first vessel remains anastomosed to the second vessel at the first and second vessel openings as the first and second rings expand and contract."

Claim 1 is nearly identical but reference is made to elements in means-plus-function format. In particular, claim 1 recites "ring means" instead of "rings."

Claim 19, as amended, recites that:

> "at least one ring is configured to radially expand to a deployed position after the first vessel and second vessel are anastomosed together such that each ring and vessel opening has a greater diameter than the initial diameter of each respective ring and vessel opening, and such that each ring and vessel opening

can then further radially expand and radially contract in response to changes in fluid pressure."

As amended, claim 18 is nearly identical to claim 19 but reference is made to "ring means" instead of "rings" as the claim recites some elements in means-plus-function format. Independent claim 20 recites that "the plurality of flexible segments of each ring are configured to enable each respective ring opening and respective vessel opening to change in diameter as each ring expands and contracts in response to changes in fluid pressure."

Independent claims 31 and 42 are directed to methods and recite:

"wherein each ring has a ring opening and the diameter of each ring opening varies as the rings expand and contract in response to changes in fluid pressure, and

wherein each ring is capable of expanding and contracting before the rings are locked together."

In contrast to the features recited in independent claims 1, 7, 18-20, 31 and 42, as quoted above, an embodiment of the device in Spence is described at column 13, lines 42-44 as having "little material memory in that once deformed from one shape into another, it will not move back into the first shape from the second." Another embodiment is described in Spence at column 14, lines 47-55 with a statement at line 48 that it has "essentially no material memory." Similar embodiments are described at

column 16, lines 16-17 and column 18, lines 51-62. The placement process is described at column 13, lines 47-49 wherein it is stated that:

> "[s]haping the cuff is therefore efficiently carried out by deforming it into the desired shape after it is mounted on a blood vessel. The retention means will maintain the cuff in the shaped condition."

The embodiments in Spence function like a stent which is moved from a first position to a second position and remains in the second position. No embodiments are disclosed in Spence with rings or ring means that can "expand and contract to enable each respective vessel opening to change in diameter" as recited in claims 1 and 7. Also, no embodiments are disclosed in Spence with rings or ring means that can "radially expand and radially contract in response to changes in fluid pressure" as recited in claims 18-20, 31 and 42.

As detailed in the Present Application, the ability to move while remaining anastomosed enables the device to function like a living junction which is particularly important for blood vessels such as arteries which change significantly in diameter due to the beating of the heart. The devices disclosed in Spence do not provide a basis for overcoming the obstacle of retaining the tissue of the vessels on the rings while also permitting expansion and retraction. There is no rationale under MPEP § 2143, or elsewhere, that could reasonably be applied to find the recited features obvious based on Spence alone or in combination with any of the other references of record. In fact,

since one of the stated functions of the devices in Spence is one-way movement to set the size of the devices, one of ordinary skill in the art would be led away from a device capable of moving as recited in the claims based on the devices in Spence.

Independent claims 7, 19 and 20 recite that "the first ring and the second ring are configured to hold the first vessel and second vessel together without requiring penetration of at least one of the vessels." Independent claims 1 and 18 recite the same feature with reference to "ring means" instead of a ring. Claims 41 and 52 recite this feature as additional limitations of the independent method claims. Spence teaches away from merely holding the vessels as indicated at column 5, lines 11-19 and column 12, lines 19-56. For example, Spence discusses specific drawbacks of "holding" at column 12, lines 24-36. Spence makes it clear that the only way for vessels to be anastomosed is to abut the ends of the vessels, with no eversion, and rely on penetration to keep the tissue in place. On this basis, in light of Spence, one of ordinary skill in the art would not look to references such as Sauer or U.S. Patent No. 3,048,177 issued to Takaro, which do not necessarily require penetration of a vessel.

Further, devices such as those disclosed in Sauer and Takao do not need to flex. The device disclosed in Sauer does not need to flex as it was developed for anastomosing intestines. Takaro provides a structure for more easily suturing blood vessels together and then the device is removed so the device in Takaro also does not need to flex. Keeping vessels anastomosed together while the device expands and

contracts is difficult enough but this achievement is even more difficult when the vessels are not penetrated, as recited in the claims. Based on Spence, one of ordinary skill in the art would expect it to be necessary for a vessel to be penetrated if it is moved. Knowledge of non-penetrating devices which are incapable of moving in the manner recited in the claims combined with devices such as those disclosed in Spence do not make the claimed inventions obvious to one of ordinary skill in the art. Even if the devices disclosed in Spence could be modified to move in the recited manner, one of ordinary skill in the art would not predict the recited structure, function and methods based on the combinations of cited art due to the difficulty of allowing the vessels to move while also holding the vessels together without requiring penetration of at least one of the vessels.

Claims 11, 39-40, and 50-51 were rejected under 35 U.S.C. § 103 as being unpatentable over Spence in view of Sauer and further in view of U.S. Patent No. 5,868,763 issued to Green et al (hereinafter "Green"). Claim 11 recites that "an intimal layer of the portion of the first vessel defining a first vessel opening contacts the portion of the second vessel defining a second vessel opening." Green clearly shows that the outside of one end of a section of the intestine is put in contact with the outside of an end of another section of the intestine. It is not possible for an intimal layer to be positioned as recited in claim 11 using the device disclosed in Green. Also, Spence teaches against this configuration as indicated at column 5, lines 11-19 and column 12,

lines 19-56. Claims 39 and 50 both recite that "the second vessel is positioned on the second ring while simultaneously locking the first and second rings together" meaning that the positioning and locking occur at essentially the same time. FIGS. 2-3 and FIGS. 11-14 of Green clearly show that the sections of the intestine are first positioned on the rings before any rings are locked together. Claims 40 and 51 are patentable for at least the reasons set forth above with respect to the independent claims. Accordingly, the claims rejected based on Green are also patentable over the cited references.

CONCLUSION

All of the dependent claims are patentable for at least the reasons provided above with regard to the independent claims. In view of the foregoing, the Applicants believe that the Application is in form for allowance. The Examiner is encouraged to contact the Applicants' undersigned attorney if the Examiner believes that any issues remain regarding the allowability of this Application.

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